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OCT 25 2005

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In re Application of  
Shiau et al  
Serial No. : 09/830,693  
Filed : March 30, 1999  
Attorney Ref No. : 61040-0013

Decision on Renewed Petition

This letter is in response to the Renewed Petition under 37 C.F.R. 1.144, filed on 3 October 2005, to request the review of the restriction requirement and the petition decision.

**BACKGROUND**

A review of the file history may be found in the petition decision mailed 2 August 2005.

The groupings of the lack of unity determination mailed to applicants on 25 June 2004 and as modified in the petition decision are as follows:

Group I, claims 1-25, 72-133, and 140-141, drawn to methods of identifying compounds which modulates nuclear receptor activity or modulates binding of a ligand to a nuclear receptor, classified in class 703, subclass.

Group II, claims 29-33, 67-71 and 134-135 drawn to a method of modulating nuclear receptor activity in a mammal, classified in class 424, subclass 198.1. This Group is subject to election of species, as set forth below.

Group III, claims 34-35 and 39, drawn to a machine readable storage medium capable of graphical three-dimensional representation, classified in class 702, subclass 27.

Group IV, claims 40-43, drawn to a machine readable storage medium comprising a program for correspondence of data, classified in class 708, subclass 403.

Group V and VII, claims 44-48, 50, 136-139 and 142-148, drawn to a crystal comprising

a portion of an estrogen receptor and an agonist and a crystal comprising a portion of an estrogen receptor and an antagonist, classified in class 350, subclass 399.

Group VI, claims 49 and 51, drawn to a crystal comprising a portion of an estrogen receptor and an antagonist, classified in class 350, subclass 399.

Group VIII, claims 52-66, drawn to a computational method of designing a nuclear receptor ligand, classified in class 703, subclass 12.

A first office action on the merits was also mailed as a part of this same communication, in which claims 48, 50 and 136-138 and 142-148 were rejected under 35 USC 112 1<sup>st</sup> and 2<sup>nd</sup> paragraphs, and claims 136 and 137 were rejected under 35 USC 102(e).

In response to the non-final rejection of 9 December 2004, applicants responded with the instant petition, accompanying arguments and amendments of the claims on 9 March 2005.

On 2 August 2005, the Office mailed applicants a decision granting the petition in part.

A Renewed Petition under 37 C.F.R. 1.144, was filed on 3 October 2005, to request the review of the restriction requirement and the petition decision.

## **DISCUSSION**

The application, file history, first and second petition under 37 C.F.R. 1.144, to request review of the lack of unity determination have been considered.

This letter is in response to the renewed Petition under 37 C.F.R. 1.144, filed on 3 October, 2005, to request rejoinder of claims 1-25, 29-35, 39, 52-133 and 140-141 from Groups I, II, III, and VIII into a single group, at such time as any of groups I, II, III and VIII is elected for further prosecution. Applicants submit that according to the Examiner's own identification of a "special technical feature" in the claims of Groups I, III and VIII, at least claims 29-33 and 67-71 of Group II should properly be examined with one of groups I, III or VIII.

Applicants additionally believe that the grounds for separating the claims of Groups I, II, III and VIII are improper according to practice under PCT Rules 13.1 and 13.2 because claims in Groups I, III and VIII, and at least claims 29-33 and 67-71 in Group II possess the following special technical features and accordingly should be joined into a single group:

An atomic structural model of the estrogen receptor ligand binding domain, comprising atomic coordinates of: helix 12 of the ligand binding domain; a coactivator binding site and a coactivator bound to the coactivator binding site

Applicants' complete argument concerning Groups I, III and VIII has been considered, and found persuasive. Groups I, III and VIII will be rejoined. Had applicants elected any one of

Group I, III and VIII for prosecution in this national stage filing of the PCT, these inventions would have been examined together.

Applicants are reminded, however, that because only a single national phase application may be filed under 35 USC 371 as a result of each international application, and because applicants have elected Group V in the instant application, any subsequent divisional applications would be filed under 35 USC 111(a) and would be subject to U.S. restriction practice rather than PCT unity of invention practice.

Applicants' complete argument concerning rejoinder of Group II, claims 29-33, 67-71 and 134-135, to Groups (I, III and VIII) has been considered, however, is found non-persuasive because the invention of Group II, taken as a whole, does not require the special technical feature of:

An atomic structural model of the estrogen receptor ligand binding domain, comprising atomic coordinates of: helix 12 of the ligand binding domain; a coactivator binding site and a coactivator bound to the coactivator binding site.

In support of this position, Claims 134-135, which are grouped with Group II are reproduced below:

134. (Withdrawn) A method of modulating estrogen receptor activity in a mammal by administering to a mammal in need thereof a sufficient amount of a compound that fits spatially and preferentially into an atomic structural model of a ligand binding domain of the estrogen receptor wherein said compound is designed so that binding of a coactivator to a coactivator binding site on the ligand binding domain is affected.

135. (Withdrawn) The method of claim 134 wherein said compound is an antagonist and binding of a coactivator is inhibited.

PCT Rule 13.2 requires that the special technical feature be shared by the inventions, taken as a whole. The presence of claims 134-135 in Group II demonstrate that the invention of Group II does not required the special technical feature shared by Groups I, III and VIII. Therefore, unity of invention is lacking between Group II and Groups (I, III and VIII).

## DECISION

The renewed petition under 37 C.F.R. 1.144 is **GRANTED-IN-PART**.

The request for rejoinder of claims 1-25, 34-35, 39, 52-66, 72-133 and 140-141 from groups I, III and VIII into a single group is **GRANTED**.

The request for rejoinder of claims 29-33, 67-71 and 134-135 from group II to rejoined Groups (I, III and VIII) is **DENIED**, because Group II, taken as a whole, does not require the special technical feature of Groups (I, III and VIII).

Applicants are again reminded, however, that because only a single national phase application may be filed under 35 USC 371 as a result of each international application, and because applicants have elected Group V for examination in the instant application, any subsequent divisional applications would necessarily be filed under 35 USC 111(a) and would be subject to U.S. restriction practice rather than PCT unity of invention practice. This decision for the unity of invention petitioned herein would not be binding for any requirement for restriction on an application filed under 35 USC 111(a).

Applicants remain under obligation to respond to the Office action mailed 8 August 2005 and re-mailed 15 August 2005 within the time period set or as extendable under 37 CFR 1.136(a).

No fee is required to review a petition filed under 35 USC 1.144. The amount of \$130.00 which was inadvertently collected by the Office in March 2005, will be credited to Applicants Deposit Account No. 06-1050.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.



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